

REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 1-22, 24 and 26-31 were examined and rejected. Claims 23 and 25 were withdrawn by the Examiner. Should a claim that is generic thereto be found allowable, rejoinder of claims 23 and 25 is requested.

By this Amendment, claims 4, 5, 13, 14, 26 and 27 have been cancelled without prejudice, and claims 1, 10 and 19 have been amended. Support for the amendments is found throughout the specification in the originally filed claims. Accordingly, no new matter has been added.

Applicants respectfully request entry of the amendments and allowance of the claims.

Rejections

All of the rejections are based on Bachinski. Yet, this reference fails to teach at least two important aspects of the claimed invention.

(1) Bachinski does not disclose each of (a) a plunger or inserter and (b) a tissue dilator as required by all of the pending claims. The claims are clear that the plunger/inserter and dilator are distinct pieces. The same is true of what is shown in the figures and discussed in the associated text.

Yet, the Examiner has said that component 412 serves as a tissue dilator and the tubular portion as a plunger/inserter. The claims do not cover a system in which there is a combination dilator/plunger. Thus, the claims cannot be anticipated by such an element.

If the Examiner is to accept this (intended) reading of the claims, the rejection(s) should be withdrawn.

As the distinguishing nature of providing for separate plunger/inserter and sheath elements, it is asserted that one would not be motivated to separate member 412 into discrete elements. Even if there were some potential motivation, doing so would produce a non-functional – even dangerous – device, since there would be nothing to hold the dilator from slipping off wire 150 inadvertently. Certainly, it is asserted that there can be no motivation to modify the device still further, when there is no purpose for the original modification of making parts separable in the first place.

(2) Both claims 1 and 19 have been amended to require that the sheath and plunger or inserter be “split or splittable” to enable the required “removal from around the graft.” As such, the amendment merely makes specific the adaptation otherwise required to effect such action. Modification of Bachinski or interpretation of the reference to meet the new limitations and noted functional requirements of the system is believed improper.

For one, Applicants assert that the Examine has improperly invoked the notion of inherency in rejecting claim 4-5, 13, 14, 29 and 27. A “splittable” structure in the medical arts has a well understood meaning. This meaning does not involve whether a material is soft, semi-rigid, etc. It has to do with the ability to effectively pull the material apart in a medical procedure. In fact, a “soft” material may be the least “splittable” of all because it might be more prone to simply stretch. In any case, it is suggested that the Examiner refer to the MPEP for the proper standard of inherency if its assertion is to be maintained.

Secondly, the members in Bachinski are part of a catheter system adapted for a percutaneous procedure in which the sheath 440 serves as a guiding catheter. Applicants are aware of no example of a split or splittable guiding catheter or what purpose that such a device would serve. If the Examiner sees the situation otherwise, it is requested that he so-state in support of a rejection to be maintained as to why one would split (or make splittable) the specific element 440 in Bachinski in the context of what the patent actually teaches.

Third, as for the physical requirements of providing a splittable introducer or plunger – based on the thick-walled configuration of element 412 in Bachinski – inherency or modification of that element in this regard is believed impractical, at best.

Fourth, the asserted motivation of making the sheath or plunger more easily removed in Bachinski by splitting the members has no relevance to the Bachinski’s teachings. Since the entire device must be withdrawn from a guiding catheter 210 to effect withdrawal from the body, it is unclear to Applicants how providing a splittable system in Bachinski would serve the asserted motivation. Unless or until some applicable motivation is provided in support of the rejection, it is asserted that no *prima facie* §103 rejections have been made.

If the rejection is to be maintained against claims noted above, applicant respectfully requests that the Examiner carefully address each of these four points in order that informed prosecution of the application might proceed.

Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number CNVG-004US1DIV.

Respectfully submitted,
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